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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,513	12/21/2004	Jeremy Marshall	3003-1159	8360

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YOUNG & THOMPSON  
209 Madison Street  
Suite 500  
Alexandria, VA 22314

EXAMINER
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SONNETT, KATHLEEN C

ART UNIT	PAPER NUMBER
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3731

NOTIFICATION DATE	DELIVERY MODE
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05/05/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/518,513	<b>Applicant(s)</b> MARSHALL, JEREMY	
	<b>Examiner</b> KATHLEEN SONNETT	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/26/2009</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 15 is objected to because of the following informalities:
  - a. Line 4: "the base portion" should read "a base portion"
  - b. Line 5: "the pointed needle tip" should read "a pointed needle tip"
  - c. Line 8: "the end of the guard" should read "an end of the guard"
  - d. Line 17 "is bridged" should read "are bridged"

Appropriate correction is required.

### ***Double Patenting***

2. Applicant is advised that should claim 18 be found allowable, claim 20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 12, 14, 15, and 18-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Higgins (US 3,358,689) in view of Morita (US 5,628,765). Higgins discloses a lancet comprising a needle (20a or 20b) having a pointed tip, a support body (11a or 11b) enclosing the needle such that the pointed tip projects beyond the end of the support body, and

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a removable guard (30a or 30b) located over the pointed tip of the needle, the guard made from molded plastics material and connected thereto by a breakable neck portion (portion of 35a or 35b). The removable guard portion has a region of thinner section (tab 30a) and a tip encasing region (35a around tip) encasing the tip of the needle wherein the tip encasing region is thicker than the thinner section (see fig. 10 and 13). The thinner central section substantially surrounds the tip encasing region and the tip of the needle as shown in the embodiments of figs. 10 and 11. Higgins discloses that various parts of the device are made from molded plastics and the guard is integrally molded with the support body. Higgins fails to disclose the claimed peripheral thickened rib.

5. Morita teaches that it is well known to include a u- or c-shape peripheral thickened rib around a central region of thinner section on a removable guard ("98"; fig. 10 and 11). The thickened rib is advantageous because it facilitates gripping of the guard for its removal. It would have been obvious to one skilled in the art to add such an outer peripheral thickened rib as taught by Morita to the device of Higgins so that it too would have this advantage. The tip encasing region is spaced from the adjacent ends of the rib such that there are respective gaps therebetween bridged only by the thinner central section. The rib will partly surround the thinner central section of the tab since it goes around the outer edge of the guard.

6. Regarding claims 18 and 20, the thickened ribs are disposed beside the needle (next to an end side) and are therefore disposed laterally of the needle. The end of the needle can be considered a side of the needle. The ends can be considered laterally adjacent to a side of the needle since they are near a side of the needle.

7. Regarding claims 15 and 19, Higgins discloses a method of forming a lancet comprising holding the needle in a mold formed to create a support body for holding the base portion of the needle and a removable guard about the needle tip and to form a breakable neck portion

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between the support body and the guard, the mold having an entry point (88) for plastics material at the end of the guard remote from the needle point. Higgins discloses injecting plastic into the mold via the entry point to create a guard about the needle tip. The mold of Higgins is used to form a lancet whose shape matches that of the mold. Higgins in view of Morita as discussed above makes obvious a lancet having an outer peripheral thickened hollow rib of generally u or c-shape and a thinner section approaching the needle tip and a further enlarged region encasing the needle tip. In order to make these shapes, it would have been well within the purview of one skilled in the art to have formed the mold with the claimed shape in order to have such corresponding features on the lancet.

8. Regarding claim 19, as discussed above, the ends of the rib are disposed laterally the needle.

9. **Claims 13 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Higgins in view of Morita as applied to claim 12 above and further in view of Crossman (GB 2,352,403). Higgins in view of Morita discloses the invention substantially as stated above except for a hole positioned close to the end of the guard remote from the needle point.

10. Crossman discloses that it is well known to have a hole (8) formed in the distal end of a plastic injection-molded guard (figs. 1-3). Adding such a hole to the modified device of Higgins would have been an obvious modification because the hole does not interfere with the encasing of the needle tip and advantageously decreases the amount of material needed to manufacture the guard. Regarding claim 17, the guard is tab-like with a thickened rib as taught by Morita.

11. **Claim 16** is rejected under 35 U.S.C. 103(a) as being unpatentable over Higgins in view of Morita as applied to claim 15 above, and further in view of Crossman (GB 2,352,403).

Higgins in view of Morita discloses the invention substantially as stated above except for a hole

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positioned close to the end of the guard remote from the needle point as well as a pin to cause the plastics material to flow around pin, thereby forming the hole.

12. Crossman discloses that is well known to have a hole (8) formed in the distal end of a guard (figs. 1-3). Adding such a hole to the modified device of Higgins would have been an obvious modification because the hole does not interfere with the encasing of the needle tip and advantageously decreases the amount of material needed to manufacture the guard. Crossman discloses that pins can be used to form holes in an injection molded plastics body (p. 3 ll. 7-9) and it would have been obvious to use such a pin in order to easily form the hole in the guard.

### ***Response to Arguments***

13. Applicant's arguments with respect to the art rejections of the claims have been considered but are moot in view of the new ground(s) of rejection. Applicant's arguments regarding the appropriateness of the double patenting warning for claims 18 and 20, should one of them be found allowable have been considered but are not found persuasive. Claim 18, when written in independent form, is the same as claim 20, almost word for word. There is a slight difference in wording regarding the limitation of "the ends of the peripheral thickened rib being disposed laterally adjacent the needle" (as worded in claim 20) but this limitation provides the same structure in both claims and the word "adjacent" in claim 20 is not considered to patentably distinguish this claim from claim 18. Therefore, the double patenting warning has been presented again.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 4/27/2010

/Anhtuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
4/30/10